

LYMErix
Lyme Disease Vaccine (Recombinant OspA)
Post-licensure safety assessment

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LYMErix

Post-licensure safety assessment

- **Post-licensure commitments**
- **Passive postmarketing surveillance**
- **Additional clinical trials**

Post-Licensure Commitments

- **Study report on cellular immunity**
 - No evidence of association between vaccination and incidence of inflammatory arthropathy
- **Reproductive toxicity study in rats**
 - No maternal or fetal toxicity detected
- **Pregnancy registry**
 - No unexpected findings
- **Safety assessment cohort study**
 - Presentation by R. Platt, M.D., MSc, Professor at Harvard Medical School